

## Message Text

UNCLASSIFIED

PAGE 01 STATE 041778  
ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-06 /023 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK  
APPROVED BY OES/APT/BMP: JFRY  
DHEW/PHS/OASH/OIH: MKEFAUVER  
ARA/MEX:GFALK (INFO)

-----250132 034357 /62

P 242239Z FEB 77  
FM SECSTATE WASHDC  
TO AMEMBASSY MEXICO PRIORITY

UNCLAS STATE 041778

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, MX

SUBJECT: DEFECTIVE DIAGNOSTIC ANTI-DNA KIT (RECALL T-047-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT: DIAGNOSTIC KIT ANTI-DNA KIT, LOT 75A

MANUFACTURER: AMERSHAM/SEARLE  
RADIOCHEMICAL CENTER  
AMERSHAM, U.K.

RECALLING FIRM: AMERSHAM/SEARLE  
2636 SOUTH CLEARBROOK DRIVE  
ARLINGTON HEIGHTS, ILLINOIS 60005

REASON FOR RECALL: TESTS HAVE SHOWN THAT THE ANTI-DNA KIT, LOT 75A, WAS GIVING FALSELY ELEVATED VALUES OVER THE ENTIRE ASSAY RANGE. OTHER LOT NUMBERS ARE NOT, REPEAT NOT BEING UNCLASSIFIED

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RECALLED.

2. POST IS REQUESTED TO ASCERTAIN WHETHER OR NOT CON-SIGNEE HAS BEEN ADVISED OF RECALL BY FIRM (LETTER DATED 3 DECEMBER 1976). ANY STOCK OF LOT 75A WAS TO BE RETURNED TO: TECHNICAL DIRECTOR, AMERSHAM/SEARLE CORPORATION, 2616 S. CLEARBROOK DRIVE, ARLINGTON HEIGHTS, ILLINOIS

60005. RETURNS WERE TO BE ACCOMPANIED BY "RESTRICTED ARTICLE STATEMENT" AND ADDRESS LABEL ON OUTSIDE OF SHIPPING CARTON. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD BE REFERRED TO FIRM. CONTACT: KAREN KABAREC, 800-323-9750 OR 312-593-6300.

3. CONSIGNEE REPORTED TO BE:

MRS. CALLEJAS  
INSTITUTO NACIONAL DE ENERGIA NUCLEAR  
LABORATORIO DE DILUCION  
NUMERO 530A  
MIGUEL ANGEL DE QUEVEDO  
MEXICO 21, D.F.  
VANCE

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 24-Feb-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01-Jan-1960 12:00:00 am  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977STATE041778  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.:CCK  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770065-0045  
**Format:** TEL  
**From:** STATE  
**Handling Restrictions:** n/a  
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**Litigation Codes:**  
**Litigation History:**  
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**Message ID:** 2056c1bf-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 2  
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**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Retention:** 0  
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**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
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**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 3237480  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** DEFECTIVE DIAGNOSTIC ANTI-DNA KIT (RECALL T- 047-7)  
**TAGS:** OGEN, ETRD, EIND, TBIO, MX, US  
**To:** MEXICO  
**Type:** TE  
**vdkgvwkey:** odb://SAS/SAS.dbo.SAS\_Docs/2056c1bf-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009